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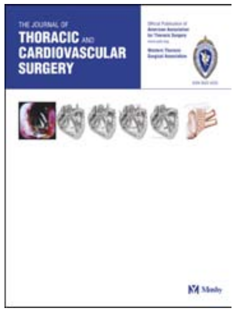

Real Time Image Integration for Transcatheter Mitral Valve Replacement in Mitral Annular Calcification

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Full title: Real Time Image Integration for Transcatheter Mitral Valve Replacement in Mitral Annular Calcification

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Central picture legend: Real time CT 3D simulation fluoroscopic fusion

Central message: Computer simulation can facilitate better patient selection for complex mitral structural interventions. Real-time fusion with fluoroscopy may optimize device deployment to targeted zones.

Mitral valve annular calcification (MAC) may involve the mitral valve architecture and result in leaflet restriction. Although in such instances conventional mitral valve replacement (MVR) surgery remains the first line treatment for stenosis and regurgitation, the presence of MAC may require surgical debridement and result in ventricular or atrioventricular groove rupture and damage to the adjacent coronary arteries. With surgical morbidity and mortality remaining high[1], there has been interest in less invasive transcatheter therapies using balloon inflatable transcatheter aortic valves. Although these have shown some early promise with reported technical success rates at specialist centers of up to 77%, periprocedural complications remain high. Immediate left ventricular outflow tract obstruction (LVOTO) occurs in up to 11.2%, a second valve is required in 14.7%, and valve embolization occurs in 4.3% of cases. Similarly, 1-year cardiovascular and all-cause mortality remain high at 23.5% and 53.7%, respectively[2,3]. These observations suggest that there may be scope to refine patient selection and better guide procedural deployment of these valves in the MAC position.

Case report

An 83-year-old man with coronary artery disease, severe mixed mitral and aortic valve disease was referred for double valve surgery and coronary artery bypass grafting. At surgery, the patient underwent aortic valve replacement with a 23 mm Trifecta™ bioprosthesis (St. Jude Medical Inc.; St. Paul, MN) and single vessel grafting to the distal right coronary artery. Owing to the degree of MAC, surgical MVR was deferred in preference for an open valvotomy. At 12 months, the patient experienced a progression of symptoms and presented to our institute for consideration of transcatheter mitral valve replacement (TMVR) with an aortic bioprosthesis within the calcification in the mitral position. Patient suitability was determined using transthoracic echocardiography to evaluate the mitral stenosis and left ventricular function, multiphase cardiac CT to characterize the MAC and its geometry (Figure 1A, B). From the CT scans, additional three-dimensional computer models of the left heart were created using image dedicated segmentation techniques (Mimics software v18.0, Materialise, Leuven, Belgium) by FEops (Ghent, Belgium). The output of this segmentation process was subsequently used to generate a finite element mesh of the complete mitral valve apparatus, including the calcified mitral valve annulus, the mitral valve leaflets and chordae tendinae. Varying mechanical properties were automatically assigned to different tissue regions. Following this, detailed computer models of the valve that accurately represented mechanical device behavior (e.g. braided wires and locking mechanism) were virtually implanted in the patient-specific left heart models using finite element simulations. All steps of the clinical implantation were respected. This included valve size selection, implantation position and computer simulation based on finite element analysis to predict calcium deformation, implantation height and LVOTO following virtual device deployment (Figure 1C)[4]. Data analysis predicted an optimal outcome for TMVR in MAC with no risk of LVOTO or paravalvular regurgitation provided that the valve was deployed at an intermediate height between the left atrium and left ventricle (Video 1).

Subsequent valve implantation was performed using a transvenous, transseptal approach under general anesthesia with real time 3D computer simulation fluoroscopic image fusion (GE Valve Assist 2, GE Healthcare, Buc, France) and transesophageal echocardiography guidance (Supplementary Material). Anatomical landmark fusion enabled optimal transseptal crossing, balloon dilatation of the interatrial septum and crossing of the mitral valve with a Safari2™ guidewire (Boston Scientific; Marlborough, MA). 3D simulation fusion was then used to align the 29 mm Edwards SAPIEN 3 valve to the optimal intermediate deployment zone, following which the valve was deployed using the nominal volume (-2 mL)**,** under rapid ventricular pacing (Figure 1D). Peri-procedural transesophageal echocardiography confirmed optimal position of the valve with no LVOTO (LVOT gradient pre-procedure 3.7 mmHg vs. 11.5 mmHg post-procedure), or paravalvular regurgitation. At 6 weeks, the patient's symptoms had improved to NYHA Class II with transthoracic echocardiography and cardiac CT showing an excellent result, consistent with the expected outcome from pre-procedural planning (Figure 1E, F).

Limitations

Currently, the application of computer simulation to patients with MAC is of investigational use only. The practicality and commercial cost of this technique cannot be answered at this stage.

Conclusions

This case demonstrates the potential of bioengineering and computer simulation to facilitate better patient selection for complex mitral structural interventions. Incorporation of this technique into real-time procedural guidance may optimize device deployment to targeted zones.

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Figure legend

Figure 1A: Cardiac CT scan 3-chamber view showing the bioprosthetic aortic valve *in situ* and the mitral valve annular calcification (*). **Figure 1B:** Cardiac CT scan short axis view at the level of the mitral valve annulus showing the heavy annular calcification, its elliptical geometry and non-circumferential distribution. The length of the anterior leaflet of the mitral valve was 22 mm. There was mild thickening at the basal septum of 14 mm but the remainder of the myocardium had normal wall thickness at 10 mm. **Figure 1C:** Computer simulated image using cardiac CT segmentation and the application of finite element analysis. The model accounts for the mitral valve annulus calcification, the mitral valve leaflets and the basal, strut and mitral valve leaflet chordae tendinae. From the model, various sizes of transcatheter valves can be virtually deployed into the mitral valve annulus at various heights, enabling prediction of calcium deformation, paravalvular regurgitation and left ventricular outflow tract obstruction. The image shows the virtual deployment of an Edwards Sapien 3 valve in the mitral valve annulus. **Figure 1D:** Real time CT 3D simulation fluoroscopic fusion showing the guidewire crossing the mitral valve. The optimal implant zone is marked by the orange and green lines (indicating the superior and inferior boundaries of the intended valve position, respectively). The undeployed Sapien 3 valve is seen being positioned between these points over the guidewire. **Figure 1E:** Post-procedural cardiac CT 3-chamber view at three months showing the deployed Sapien 3 valve in close apposition with the annulus. and there was no left ventricular outflow obstruction. **Figure 1F:** Post-procedural cardiac CT – short axis view showing the deployment of the transcatheter valve against the mitral annular calcification.

Ao – aorta, LA – left atrium, LV – left ventricle, MV – mitral valve, TMVR – transcatheter mitral valve replacement

Video legend

Video 1

Computer simulation demonstrating the deployment of an Edwards Sapien 3 valve within the mitral annular calcification at an intermediate deployment zone. The video demonstrates the expected deformation of the calcium under conditions of radial stress.

Supplemental Material

Video 2

Periprocedural transesophageal echocardiogram – 143^{o} view demonstrating the presence of mitral annular calcification, severe leaflet restriction and mitral stenosis.

Video 3

Periprocedural transesophageal echocardiogram 3D volume rendered surgical view of the mitral valve showing severe mitral annular calcification and mitral valve leaflet restriction.

Video 4

Cardiac CT fluroscopic landmark fusion showing the key anatomical landmarks from the CT scan overlaid onto the fluroscopic images. The yellow circle represents the superior vena cava boundary, the inferior green circle the inferior vena cava boundary, the light blue the mitral annular calcification, the orange central circle the fossa ovalis, the orange superior circle the aortic valve and the yellow and green vertical rings the superior and inferior boundaries of the ideal implantation zone for the Sapien 3 valve.

Video 5

Cardiac CT fluroscopic landmark fusion with the same landmark coding as Video 4. The video shows the positioning of the Sapien 3 valve at the simulated optimal position and the superimposition of the 3D volume rendered left atrium onto the fluoroscopy along with the anatomical landmarks to guide the valve deployment.

Video 6

Periprocedural transesophageal echocardiogram – 125^o view with color Doppler showing no paravalvular regurgitation across the implanted Sapien 3 valve and no left ventricular outflow tract obstruction.

Video 7

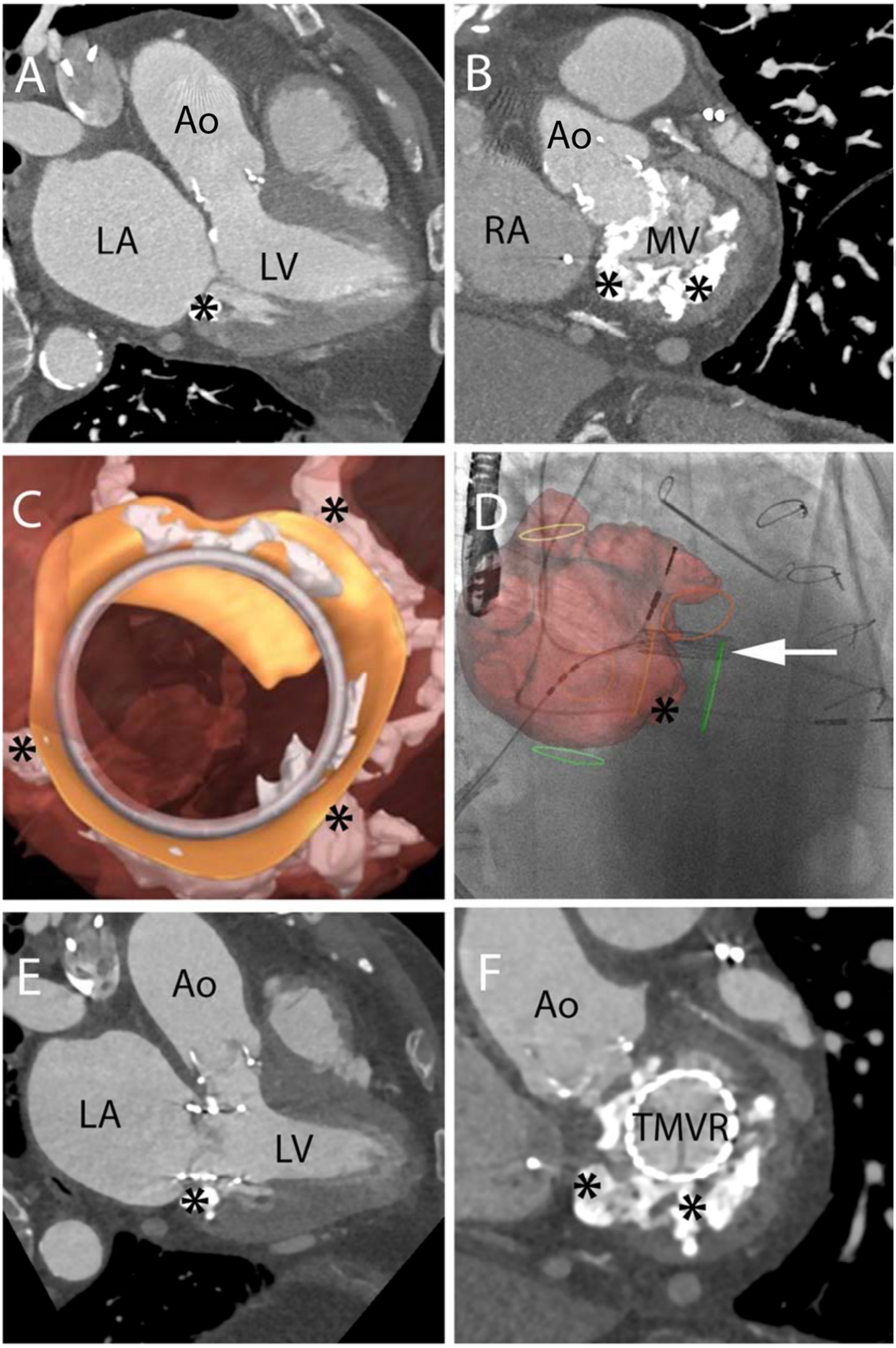
Periprocedural transesophageal echocardiogram – 3D volume rendered surgical view of the implanted Sapien 3 valve showing normal leaflet motion and good device stability.

Video 8

Post procedural transthoracic echocardiogram at 6 weeks – apical 4 chamber view with color Doppler showing no paravalvular regurgitation and no LVOTO.

Video 9

Post procedural ECG gated multiphase CT at 6 weeks showing positioning of the Sapien 3 valve at an intermediate implantation height with no significant left ventricular outflow tract obstruction in the 3-chamber view.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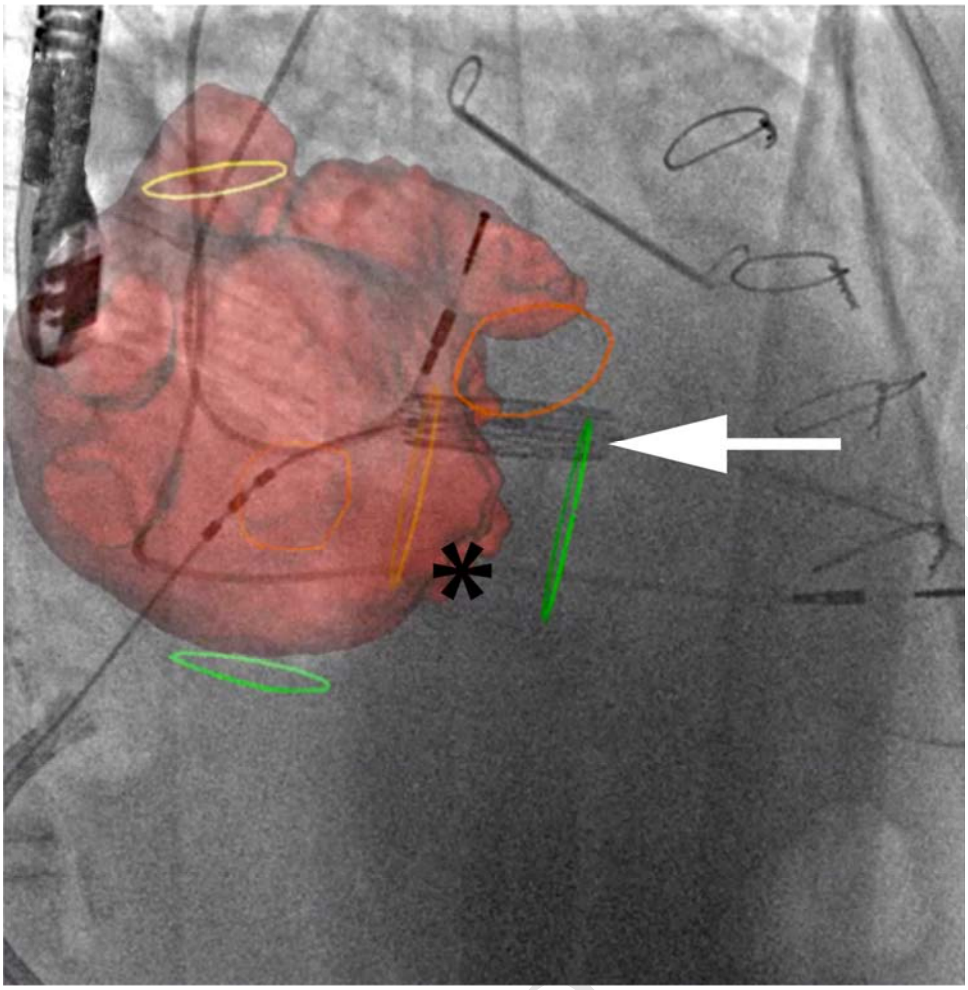

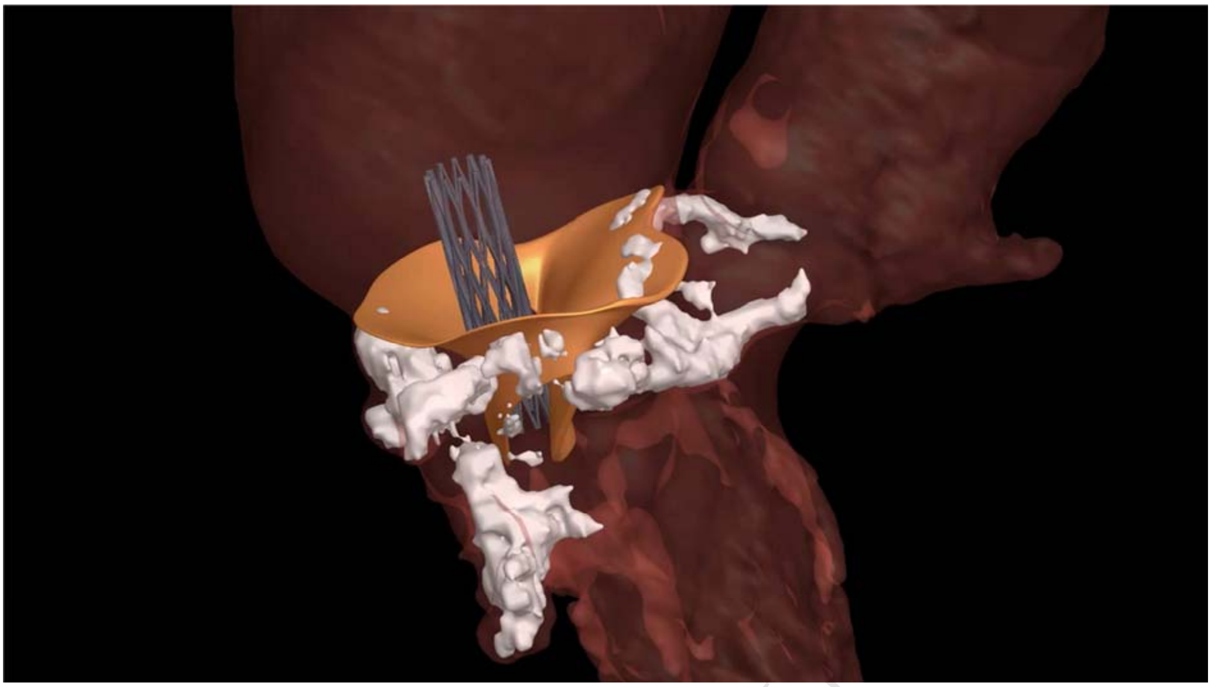

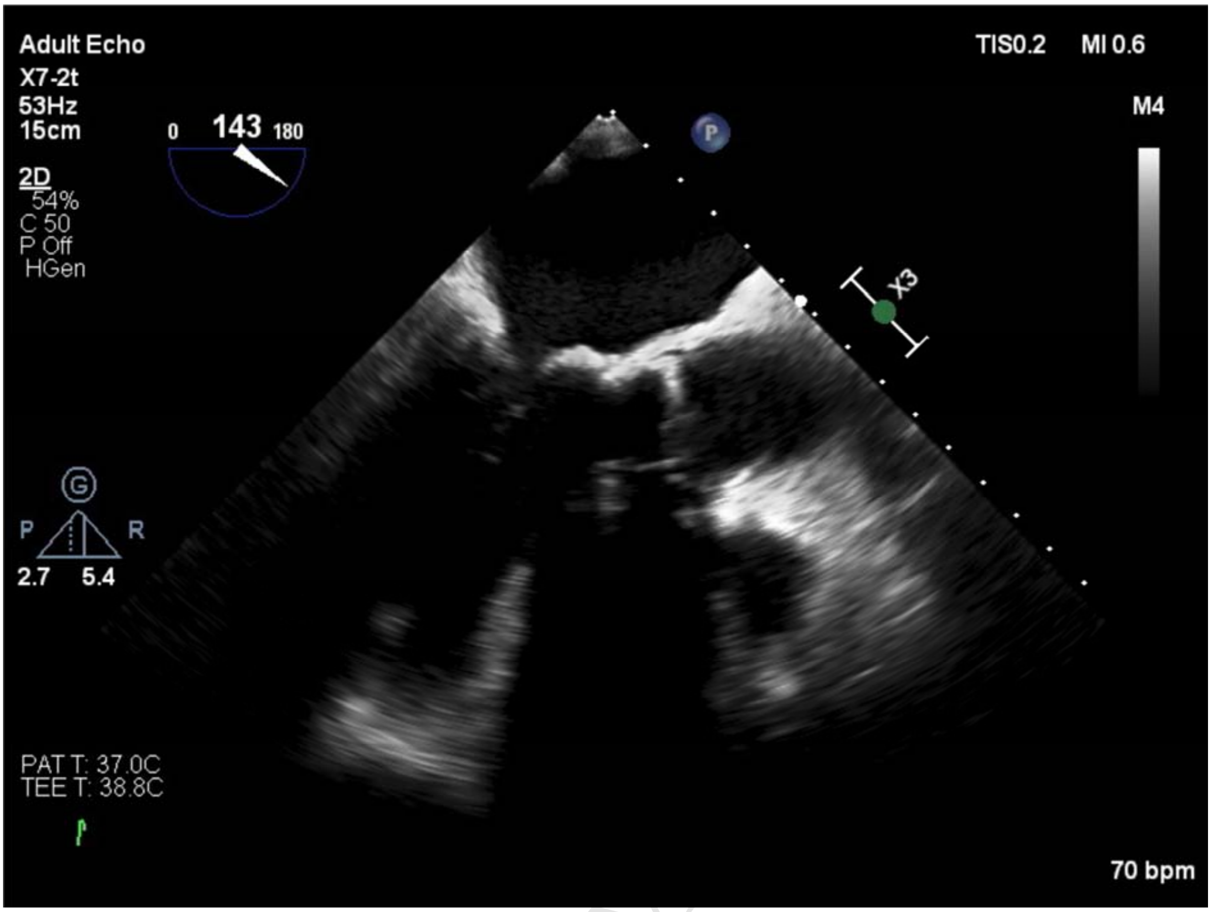
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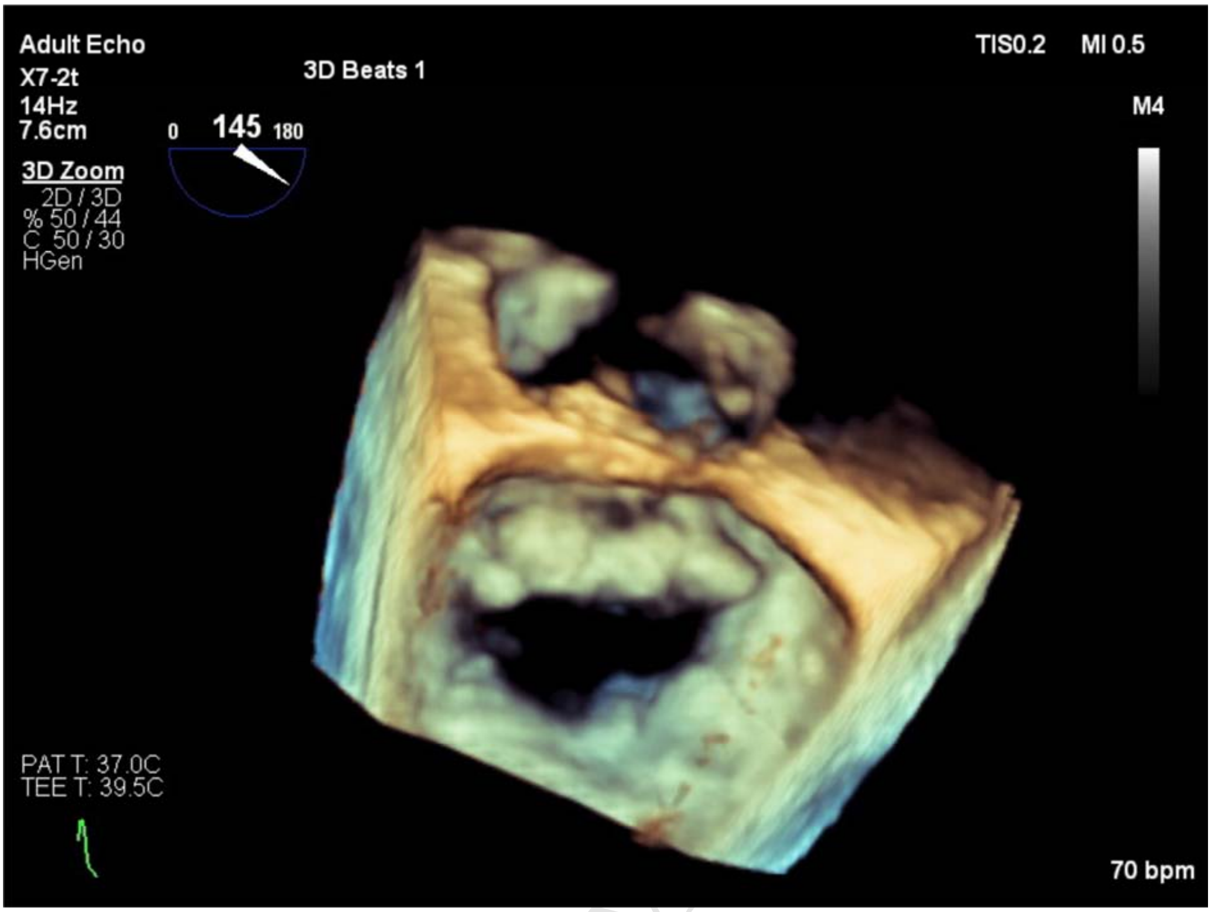
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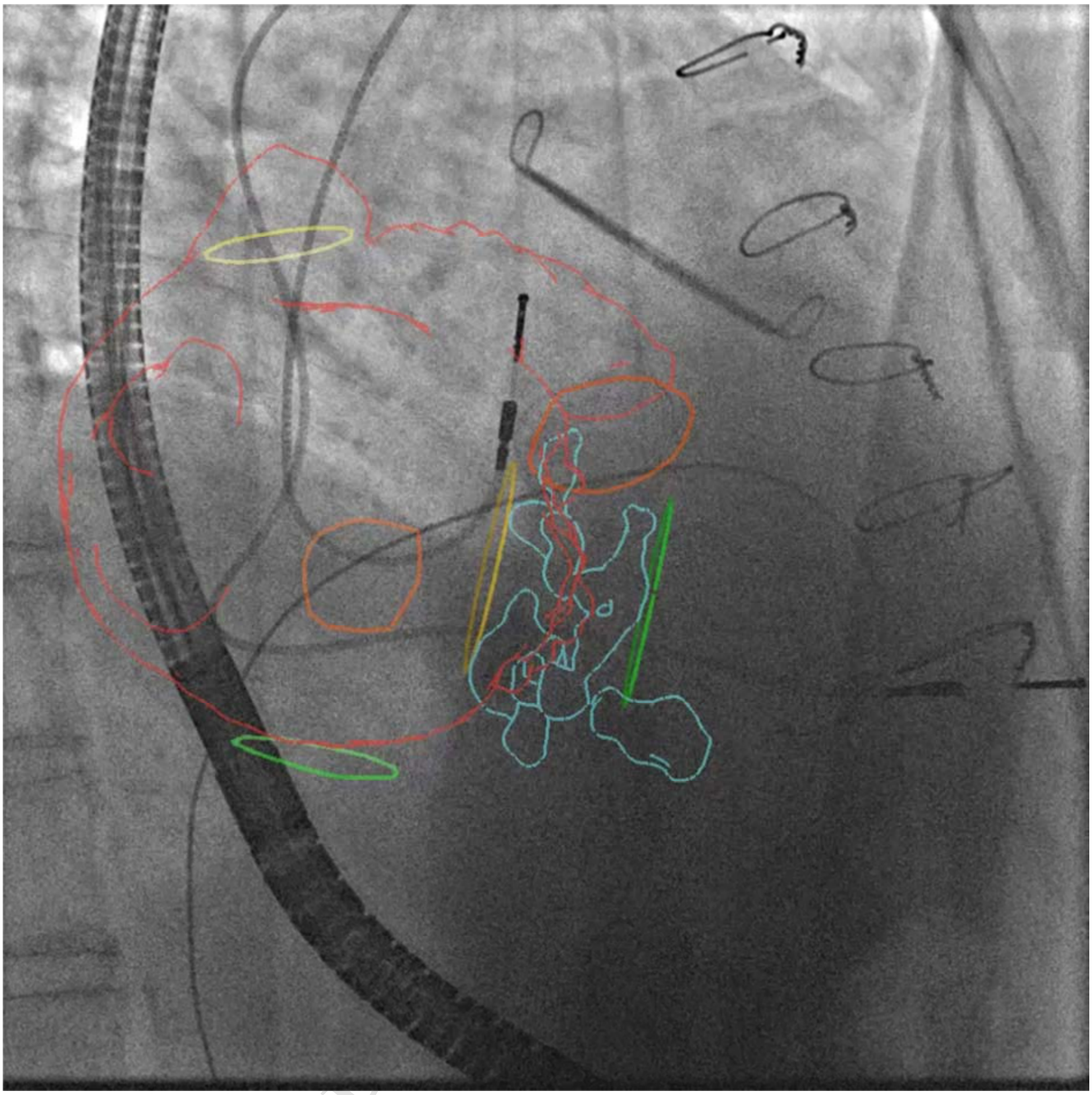

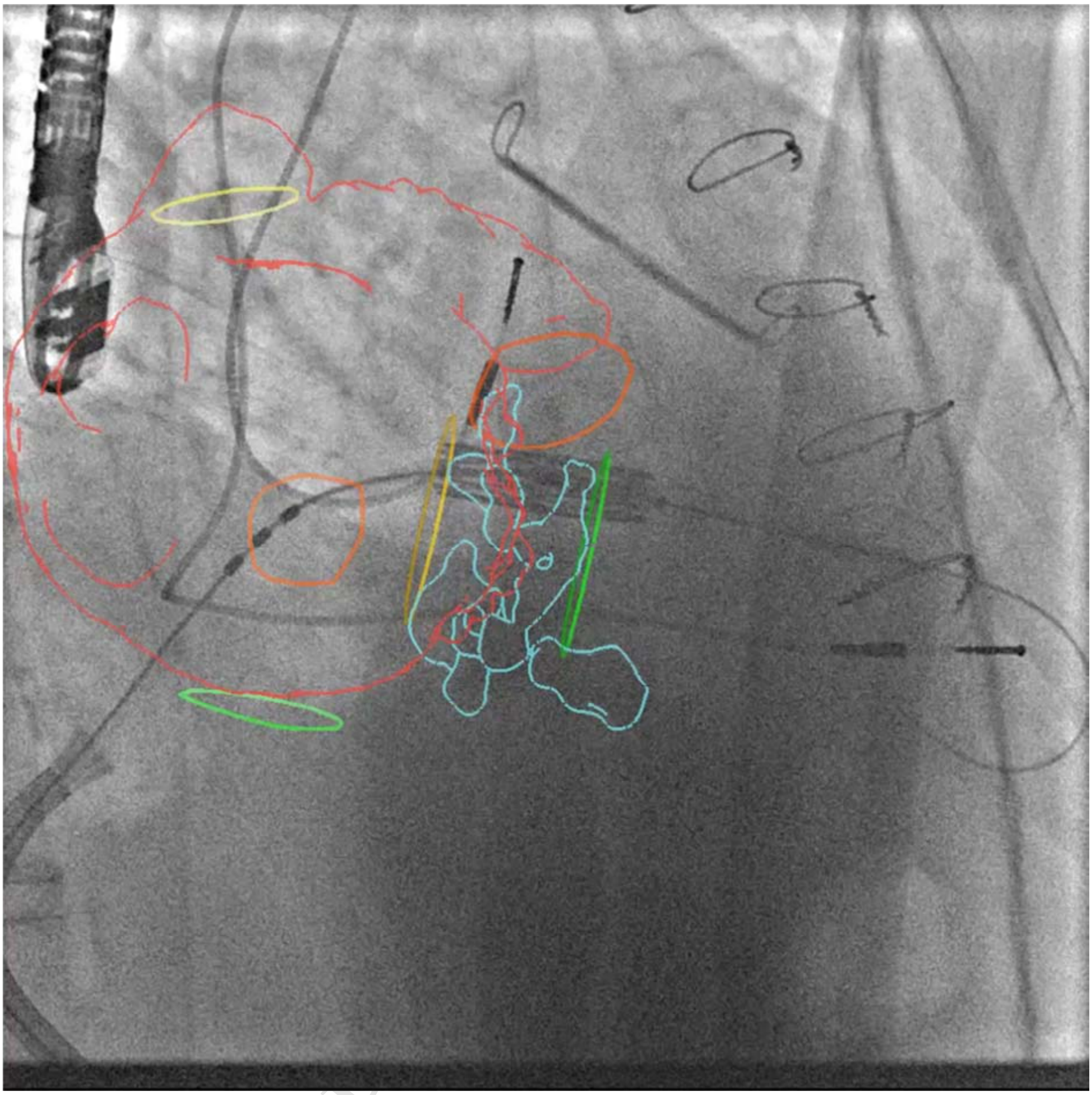

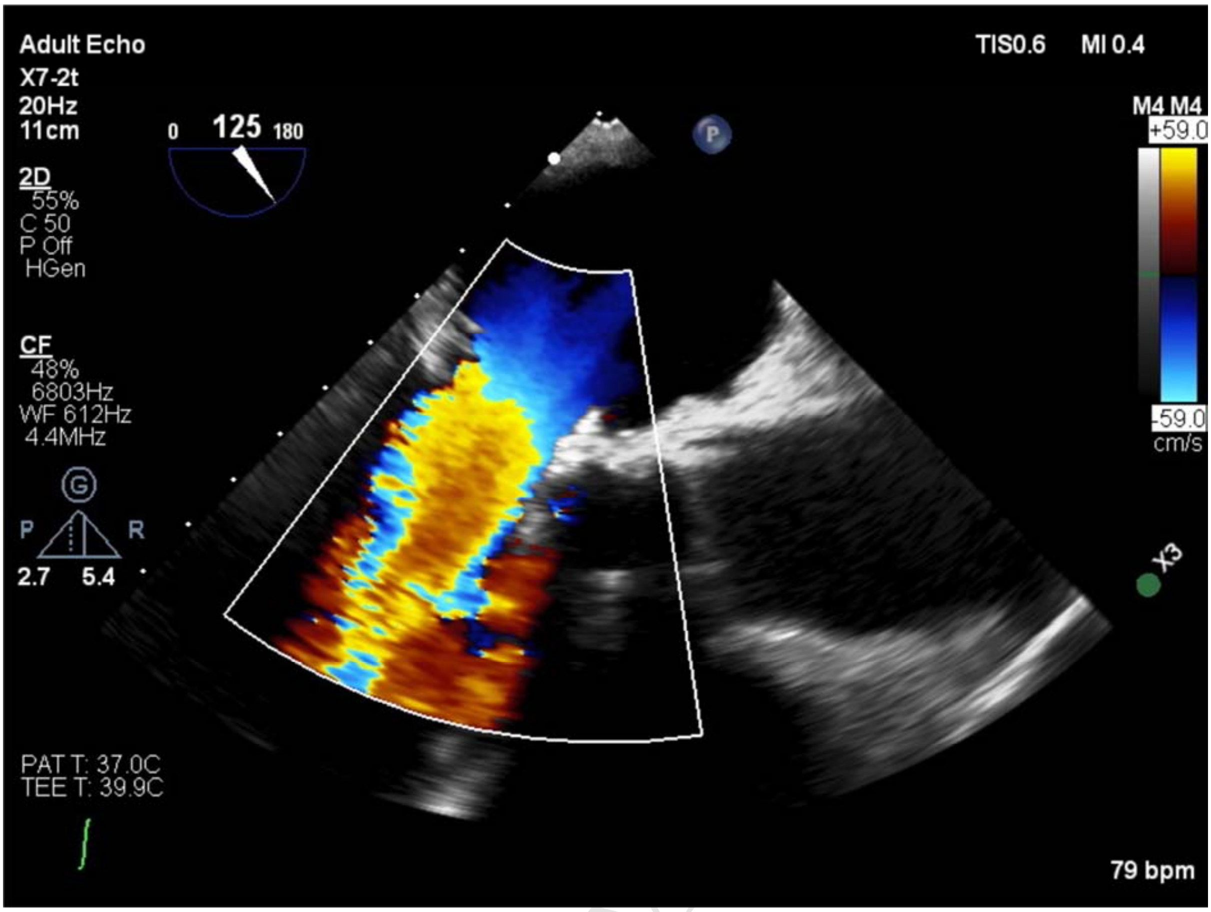

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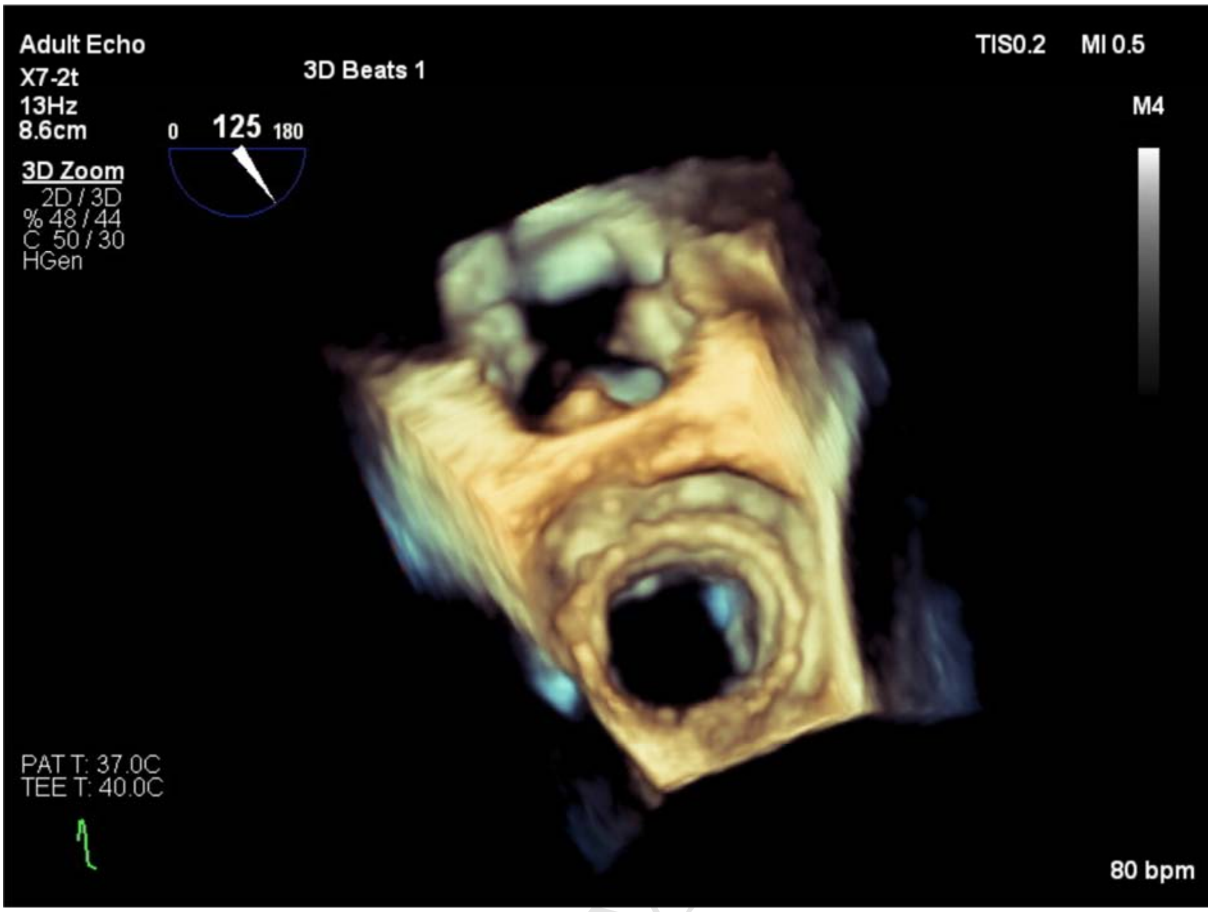

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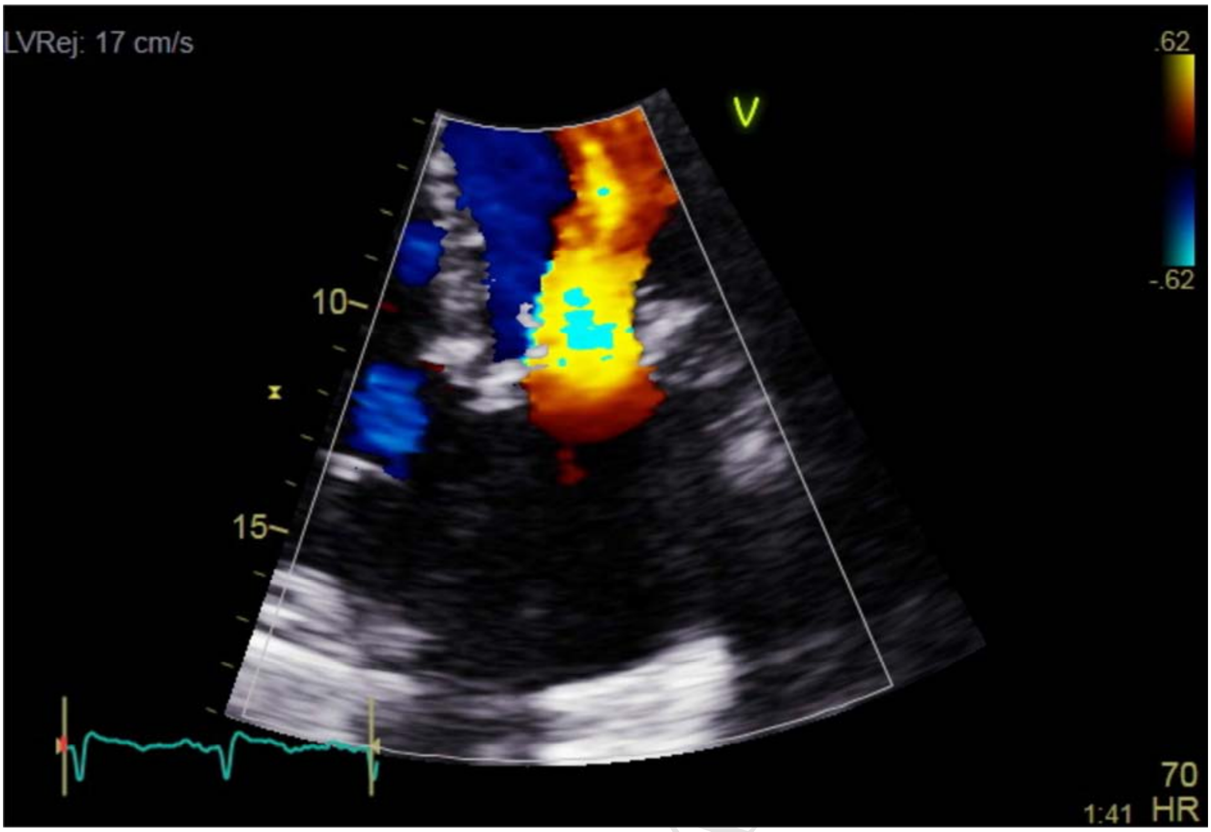
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